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Attorneys for Plaintiffs
Edwards Lifesciences LLC
and EndoGAD Research Pty Limited

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

C 03 3817

EDWARDS LIFESCIENCES LLC, and ENDOGAD RESEARCH PTY LIMITED,

Plaintiffs,

vs.

MEDTRONIC, INC., MEDTRONIC AVE, INC., COOK INCORPORATED, and W. L. GORE & ASSOCIATES, INC.

Defendants.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs, Edwards Lifesciences LLC ("Edwards"), and EndoGAD Research Pty Limited ("EndoGAD") (collectively, "Plaintiffs"), through their counsel, for their complaint state, allege, and aver as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

2. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

3. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

INTRADISTRICT ASSIGNMENT

4. This action is a patent infringement action and falls in an excepted category under the Court's Assignment Plan pursuant to Civil L.R. 3-2(c).

PLAINTIFFS

5. Edwards is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, CA 92614.

6. EndoGAD is a company organized and existing under the laws of Australia (an Australian Company ABN 51 073677611), with its registered office at Suite 1, Level 3, 55 Phillip Street, Parramatta, NSW, 2150, Australia.

DEFENDANTS

7. Medtronic, Inc. ("Medtronic") is a corporation organized and existing under the laws of the State of Minnesota, with a principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. On information and belief, Medtronic conducts business in the State of California and in this judicial district.

8. Medtronic AVE, Inc. ("AVE") is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 3576 Unocal Place, Santa Rosa, California 95403. AVE conducts business in the State of California and in this judicial district.

9. Cook Incorporated ("Cook") is a corporation organized and existing under the laws of the State of Indiana, with a principal place of business at 750 Daniels Way, Bloomington, IN 47404. On information and belief, Cook conducts business in the State of California and in this judicial district.

10. W. L. Gore & Associates, Inc. ("Gore") is a corporation organized and existing under the laws of the State of Delaware, with headquarters at 555 Paper Mill Road, Newark, Delaware 19711. On information and belief, Gore conducts business in the State of California and in this judicial district.

THE PATENT IN SUIT

11. On June 24, 2003, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 6,582,458 ("the '458 patent"), entitled "Intraluminal Graft," in the names of Geoffrey H. White and Weiyun Yu. On August 12, 2003, the United States Patent and Trademark Office duly and legally issued a Certificate of Correction for the '458 patent. EndoGAD

is the owner of the '458 patent. A copy of the '458 patent, including the Certificate of Correction, is attached as Exhibit A to this Complaint.

12. Edwards is the exclusive licensee under the '458 patent, as successor in interest to a license agreement between EndoGAD, Geoffrey H. White, Weiyun Yu, and Baxter Healthcare Corporation. Edwards and EndoGAD, collectively, have the right to make, use, sell and offer to sell the claimed invention of the '458 patent, and have the right to sue and recover for all past, present and future infringement of the '458 patent.

PATENT INFRINGEMENT BY MEDTRONIC AND AVE

13. Upon information and belief, Medtronic and AVE have been and are infringing one or more claims of the '458 patent by making, using, selling and/or offering to sell in the United States endovascular grafts for treatment of abdominal aortic aneurysms, including products sold under the names AneuRx Stent Graft and/or Talent Endoluminal Stent-Graft System, and components thereof, which embody, incorporate or otherwise practice the claimed invention of the '458 patent.

14. As a direct and proximate result of Medtronic's and AVE's infringement of the '458 patent, Edwards and EndoGAD have been and continue to be damaged in their collective business and property, including the loss of revenues in an amount to be determined at trial.

15. Edwards and EndoGAD have been and continue to be irreparably harmed by Medtronic's and AVE's infringement of the '458 patent. Medtronic's and AVE's infringing activities will continue unless enjoined by this Court.

PATENT INFRINGEMENT BY COOK

16. Upon information and belief, Cook has been and is infringing one or more claims of the '458 patent by making, using, selling and/or offering to sell in the United States

endovascular grafts for treatment of abdominal aortic aneurysms, including products sold under the name Zenith AAA Endovascular Graft, and components thereof, which embody, incorporate or otherwise practice the claimed invention of the '458 patent.

17. As a direct and proximate result of Cook's infringement of the '458 patent, Edwards and EndoGAD have been and continue to be damaged in their collective business and property, including the loss of revenues in an amount to be determined at trial.

18. Edwards and EndoGAD have been and continue to be irreparably harmed by Cook's infringement of the '458 patent. Cook's infringing activities will continue unless enjoined by this Court.

PATENT INFRINGEMENT BY GORE

19. Upon information and belief, Gore has been and is infringing one or more claims of the '458 patent by making, using, selling and/or offering to sell in the United States endovascular grafts for treatment of abdominal aortic aneurysms, including products sold under the name Excluder Bifurcated Endoprothesis, and components thereof, which embody, incorporate or otherwise practice the claimed invention of the '458 patent.

20. As a direct and proximate result of Gore's infringement of the '458 patent, Edwards and EndoGAD have been and continue to be damaged in their collective business and property, including the loss of revenues in an amount to be determined at trial.

21. Edwards and EndoGAD have been and continue to be irreparably harmed by Gore's infringement of the '458 patent. Gore's infringing activities will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, by reason of the foregoing, Plaintiffs Edwards and EndoGAD respectfully request that this Court enter a judgment against Defendants Medtronic, AVE, Cook and Gore as follows:

A. Edwards and EndoGAD collectively have the right to recover for any and all infringement of the '458 patent;

B. The '458 patent is valid and enforceable;

C. Medtronic and AVE have infringed the '458 patent;

D. Medtronic and AVE, their officers, subsidiaries, parents, agents, servants, employees, attorneys, and parent, subsidiary and affiliate corporations or other business entities, and all other persons acting in concert with them, and their successors and assigns, be permanently enjoined and restrained from further infringement of the '458 patent;

E. An accounting be had for the damages to Edwards and EndoGAD arising out of Medtronic's and AVE's infringing activities together with interest and costs, and that such damages be awarded to Edwards and EndoGAD;

F. Cook has infringed the '458 patent;

G. Cook, its officers, subsidiaries, parents, agents, servants, employees, attorneys, and parent, subsidiary and affiliate corporations or other business entities, and all other persons acting in concert with it, and its successors and assigns, be permanently enjoined and restrained from further infringement of the '458 patent;

H. An accounting be had for the damages to Edwards and EndoGAD arising out of Cook's infringing activities together with interest and costs, and that such damages be awarded to Edwards and EndoGAD;

I. Gore has infringed the '458 patent;

J. Gore, its officers, subsidiaries, parents, agents, servants, employees, attorneys, and parent, subsidiary and affiliate corporations or other business entities, and all other persons acting in concert with it, and its successors and assigns, be permanently enjoined and restrained from further infringement of the '458 patent;

K. An accounting be had for the damages to Edwards and EndoGAD arising out of Gore's infringing activities together with interest and costs, and that such damages be awarded to Edwards and EndoGAD; and,

L. Edwards and EndoGAD be granted such other and further relief that the Court may deem just and proper.

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DEMAND FOR JURY TRIAL

Plaintiffs Edwards and EndoGAD respectfully request a trial by jury pursuant to Rule 38(b) of the Federal Rules of Civil Procedure of any and all issues triable of right by a jury.

Dated: August 15, 2003

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US006582458B1

(12) **United States Patent**
White et al.

(10) **Patent No.: US 6,582,458 B1**
(45) **Date of Patent: Jun. 24, 2003**

(54) **INTRALUMINAL GRAFT**

(76) Inventors: **Geoffrey H. White**, 22 Nicholson Sreet, East Balmain, New South Wales (AU), 2041; **Weiyun Yu**, 34/2 Friend Avenue, Five Dock, New South Wales (AU), 2046

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/071,731**

(22) Filed: **May 1, 1998**

Related U.S. Application Data

(63) Continuation of application No. 08/446,672, filed as application No. PCT/AU94/00586 on Sep. 29, 1994, now Pat. No. 5,782,904.

(30) **Foreign Application Priority Data**

Sep. 30, 1993 (AU) PM1537

(51) **Int. Cl.**[7] **A61F 2/02**
(52) **U.S. Cl.** **623/1.11**; 623/1.35
(58) **Field of Search** 623/1.11, 1.12, 623/1.14, 1.15, 1.16, 1.18, 1.22, 1.23, 1.34, 1.35, 1.36

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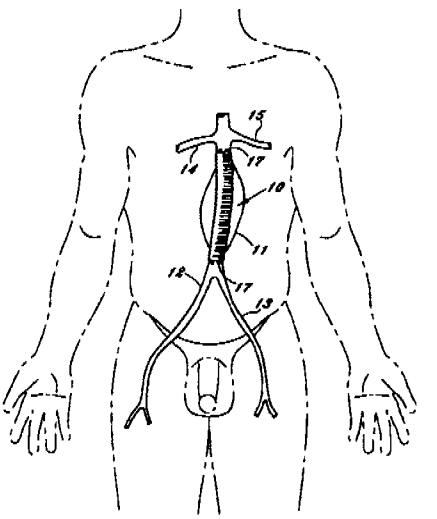
Primary Examiner—Michael J. Milano
(74) *Attorney, Agent, or Firm*—Neifeld IP Law, PC

(57) **ABSTRACT**

An intraluminal graft includes a tubular graft body extending along a cylindrical axis, a plurality of wires spaced apart from each other and arranged to circumferentially reinforce said tubular graft body along a substantial portion of its length, and a body surface including an inner surface region and an outer surface region. The body surface defines a plurality of apertures extending from an exterior space, and a first portion of a first wire is in the interior space while a second portion of the first wire is in the exterior space.

10 Claims, 4 Drawing Sheets



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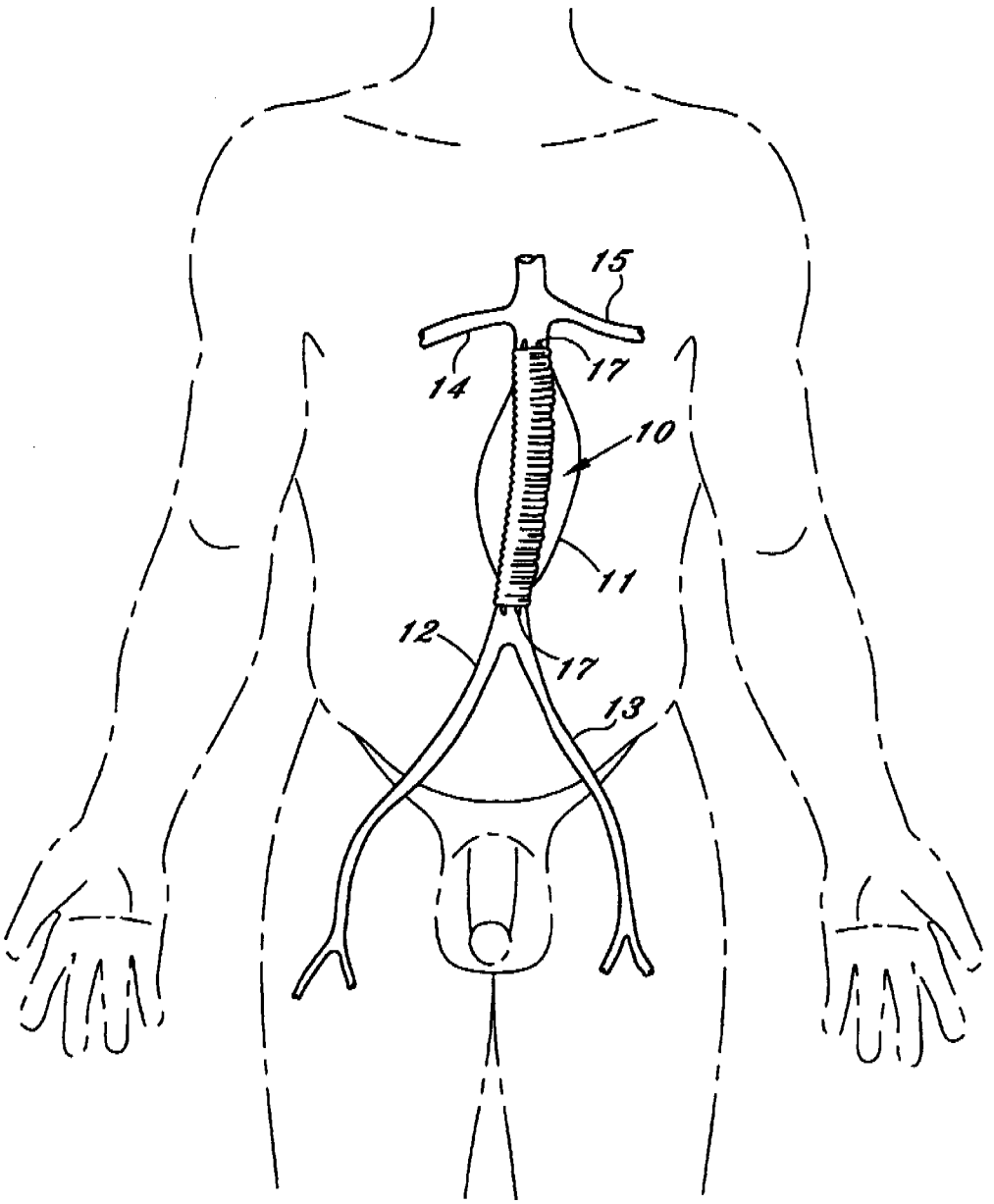

Fig. 1

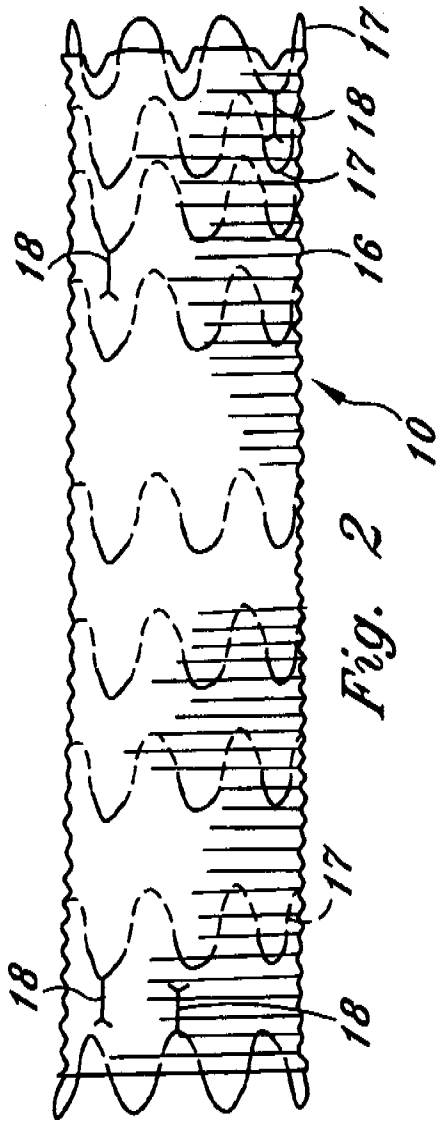

Fig. 2

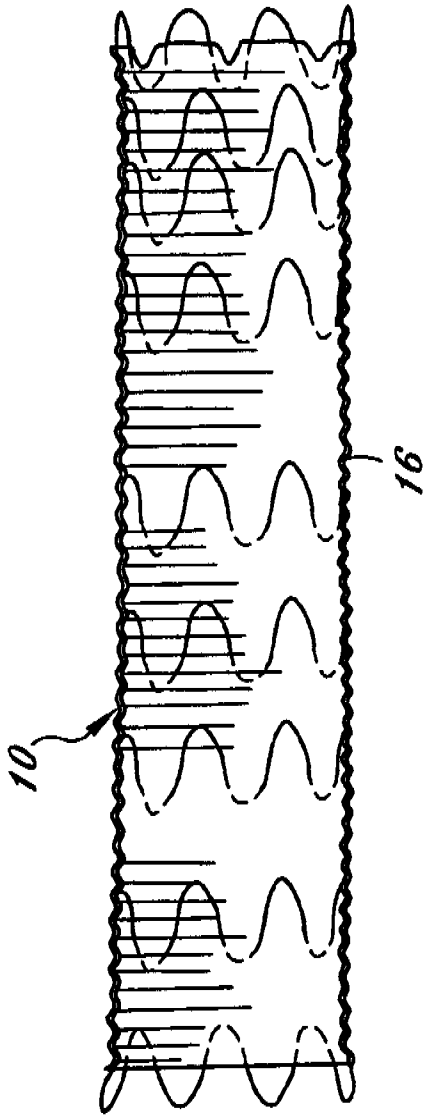

Fig. 3

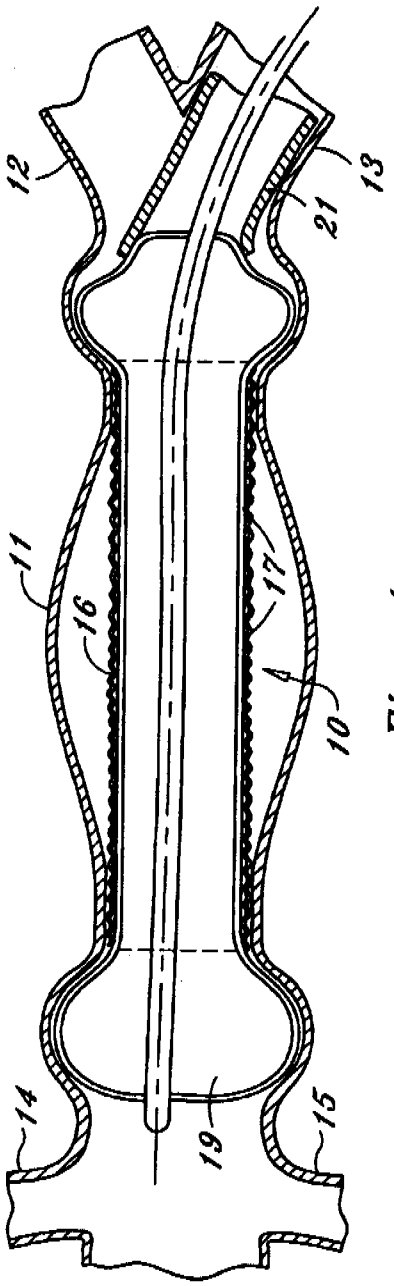

Fig. 4

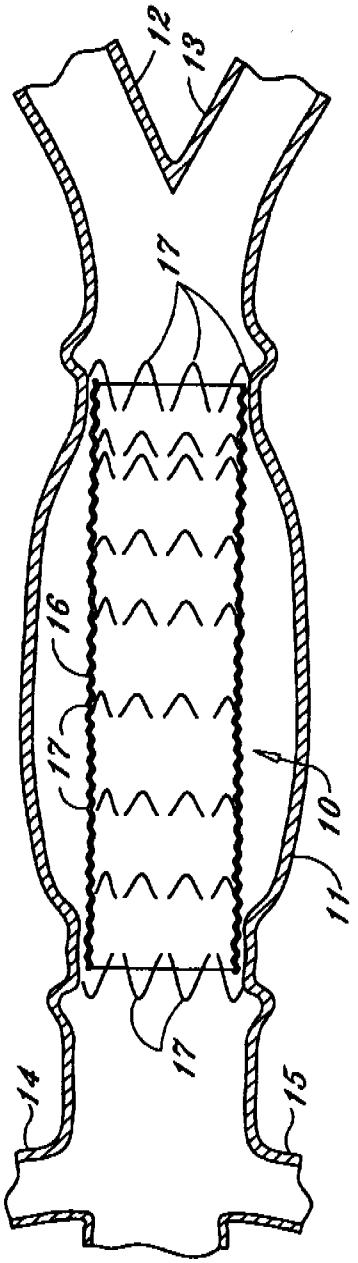

Fig. 5

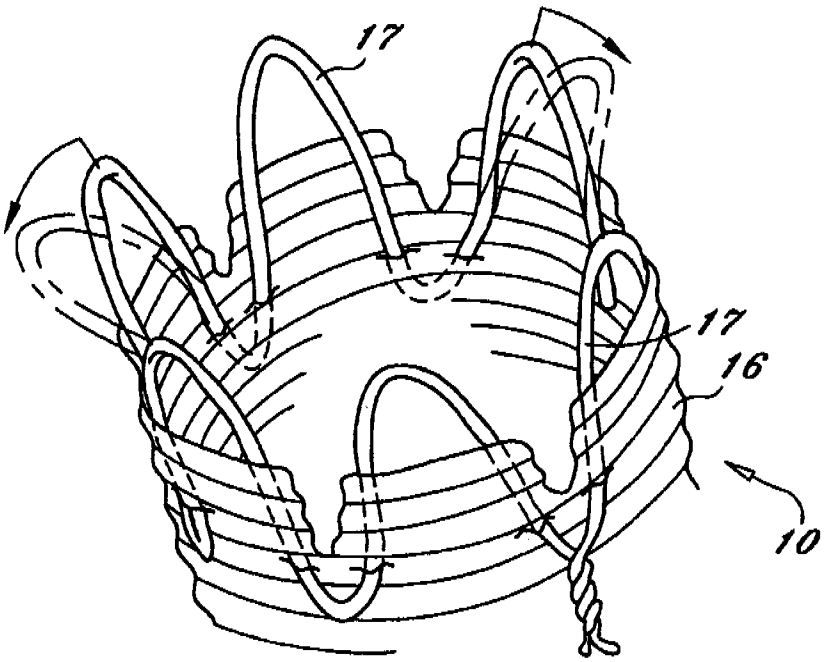

Fig. 7

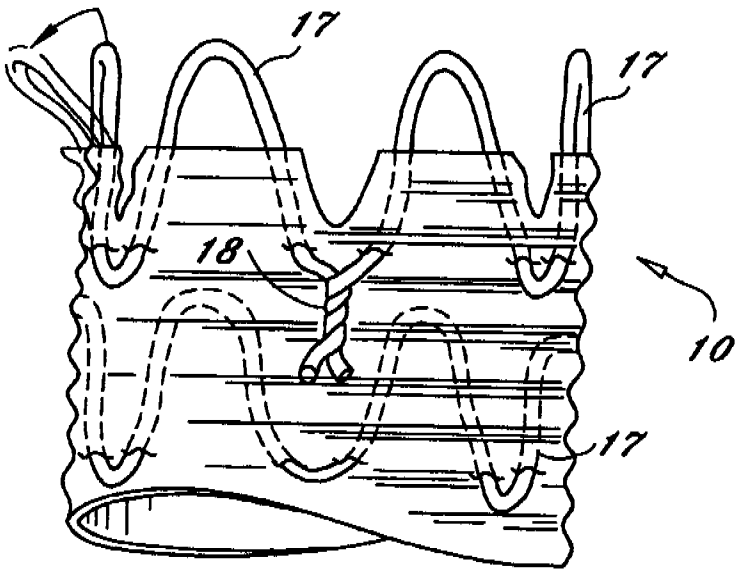

Fig. 6

INTRALUMINAL GRAFT

RELATED CASES

This application is a continuation of U.S. application Ser. No. 08/446,672, filed on Jul. 20, 1995, now U.S. Pat. No. 5,782,904, which is a national phase filing of PCT/AU94/00586, filed on Sep. 29, 1994.

FIELD OF THE INVENTION

The present invention relates to an intraluminal graft for use in treatment of aneurysms or occlusive diseases.

BACKGROUND ART

It is known to use stents and intraluminal grafts of various designs for the treatment of aneurysms such as aortal aneurysms and for the treatment of occlusive diseases such as the occlusion of blood vessels or like ducts such as the bile duct and the ureter (which are all hereinafter called "vessels"). It is known to form such an intraluminal graft of a sleeve in which is disposed a plurality of self expanding wire stents (see Balko A. et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms", Journal of Surgical Research 40, 305–309 (1986); Mirich D. et al, "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" Radiology, Vol. 170, No. 3, part 2, 1033–1037 (1989)). Such intraluminal grafts are inserted through the femoral artery into the aorta in a catheter. Upon the release of the graft from the catheter it expands to the size of the aorta above and below the aneurysms and bridges the aneurysms.

There are a number of problems associated with such known grafts. These include the problem of twisting or kinking of the graft when it has to extend along a non-linear path which, twisting or kinking can lead to occlusion of the lumen of the graft; lack of precise control of the expansion of the graft in the lumen; avoidance of inadvertent separation of a supporting stent and the covering sleeve; and maintaining the graft against longitudinal movement along the lumen in which it is placed. The present invention is directed to an alternative form of intraluminal graft which provides an alternative to the known grafts.

DISCLOSURE OF THE INVENTION

In a first aspect the present invention consists in an intraluminal graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond at least part of that end.

In another aspect the invention relates to a method for positioning an intraluminal graft as defined above comprising introducing a catheter into a vein, artery or other vessel in the body, causing an intraluminal graft as defined above to be carried through the catheter on an inflatable balloon until the graft extends into the vessel from the proximal end of the catheter, inflating the balloon to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel, deflating the balloon and withdrawing the balloon and the catheter from the vessel.

In preferred embodiments of the invention each end of the graft will be provided with a wire which has alternate crests or apices extending beyond the adjacent end of the graft body. While the graft will normally have wires at each end of the graft with their crests extending beyond the graft body it may be necessary or desirable for a surgeon to shorten a graft and this may be achieved by cutting off part of the graft body. In this case the graft will have extending crests at only one end.

The projection of alternate crests or apices of the end wire or wires beyond at least part of the end or ends of the graft body is an important feature of this invention. As the graft is expanded by a balloon the expansion of the wires, and of the balloon, will be limited by the diameter of the tubular graft body except in the region of the alternate crests or apices of the end wire or wires. The balloon will be able to expand these crests slightly more than the remainder of the wire so that they bell outwardly away from the adjacent end of the graft body. The crests are forced into contact with the wall of the vessel and thereby become at least partly embedded into the vessel wall. This belling out of the crests of the wires at one or both ends of the graft body into contact with the inside surface of the vessel wall and then being at least partly embedded in the wall will assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion. The wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen. This allows the intraluminal graft to be used in situations in which the aneurysm to be bridged commences closely adjacent divergent blood vessels. In most cases there will be crests of wire actually projecting totally beyond the end of the graft materials. It would, however, be possible to have flaps of graft material protruding up the outside of each crest even though intermediate the crests the end of the graft stops well short of the crests. In this latter arrangement the crests are still free to bell outwardly as has been described above even though the crests do not extend absolutely beyond the end of the graft.

It is preferred that the one wire has a greater amplitude than at least the next adjacent one or two wires. This allows the wires at the end of the graft to be positioned more closely together than would be the case if they were all of the same amplitude. It is desirable to space the wires adjacent the end of the graft that will be placed "upstream" in the patient as close together as is possible as the neck of the aneurysm with which the graft is engaged can be quite short. Close spacing of the wires maximises the number of wires reinforcing that part of the graft in contact with the neck of the aneurysm. The spacing of the rest of the wires is desirably greater than those adjacent the one end of the graft as this avoids unnecessarily reducing the flexibility of the graft.

The wavelength of the wires in the graft is preferably substantially the same when compressed however when expanded the end wires will have a shorter wavelength than the intermediate wires as the intermediate wires will not bear against the arterial wall and may therefore be more fully expanded.

It is preferred that the edge of the one end of the graft is scooped out or scalloped between each projecting crest of the one wire. This reduces the possibility that a piece of the graft between those crests could project into the arterial lumen and partially occlude it or direct blood around the outside of the graft.

The tubular graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE. The tube material is preferably crimped along its length to increase its flexibility, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention the graft body may be formed from a material

having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall. The length and diameter of the graft body will be determined by the individual circumstances of the application to which the intraluminal graft is to be put. Typically, the vessel will be assessed by X-ray or other similar examination and a suitably dimensioned graft selected for that application.

The wires are preferably formed of stainless steel or another metal or a plastic which is maleable and is biocompatible. Each wire is preferably woven into the fabric of the graft body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the graft body during introduction of the graft or throughout its life. If the graft body is of a woven material the wires may be interwoven with the graft body during its production or alternatively they may be interwoven with the graft body after its manufacture. If the graft body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the graft body. The interweaving of the wires with the graft body has been found to be particularly desirable as it prevents separation of the wires from the graft body which could have serious adverse consequences. It has also been found that this technique is very good for causing the graft to expand effectively with the wires.

In alternative embodiments the wires may be held in place by sutures or adhesives or may be sandwiched between layers of a multi-layered tubular graft body. In all of the foregoing arrangements the wires are preferably disposed substantially within the graft body. It is, however, within the ambit of the invention that the wires may be connected to, and be disposed on, the outside surface of the graft body.

The intraluminal grafts according to this invention may be used to treat aneurysms or occlusive disease. In addition to treating aortic aneurysms they are particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery. The presence of the metal wires in the intraluminal grafts according to this invention assists in placing the graft as the wires are X-ray detectable. As the wires are arrayed along the length of the graft the complete position of the graft in the body can be continuously monitored.

The grafts according to this invention are typically substantially of constant diameter along their length ie, they are substantially cylindrical. It is possible, however, for the grafts to be frusto-conical in shape with a diameter that increases, or decreases, along the length of the graft.

The ends of the wires are joined together to form a tail which is preferably on the outside of the graft body and is positioned to lie along its radially outer surface. The ends may be joined by welding, by being twisted together or in any other suitable manner. The ends of the wires may inadvertently perforate the vessel in which the graft is placed, however, any such perforation will be occluded by the graft body thus ensuring that such a perforation will not adversely affect the patient. The ends of adjacent wires are preferably spaced apart radially about the graft body so as not to affect its flexibility and to avoid a line of ends engaging the wall of the vessel. The ends of adjacent wires preferably project in opposite directions along the vessel body. When the intraluminal graft is inserted into a vessel those wire ends which engage the inside surface of the vessel wall will assist in preventing the graft from inadvertent movement along the vessel. Causing the ends of alternate wires to project in opposite longitudinal directions along the graft body will assist in preventing longitudinal movement of the graft along the vessel in either direction.

In some circumstances it is desirable to insert two or more overlapped intraluminal grafts according to the present invention. In this case the first or upstream graft preferably has at its downstream end a "skirt" without reinforcing wires. This skirt is typically 10 to 15 mm in length. The second or downstream graft is inserted into the downstream end of the first graft and is expanded to engage with it. There is preferably an overlap of at least 10 mm however the degree of overlap is often adjusted so that the downstream end of the second graft is correctly placed in the downstream neck of the aneurysm being treated. This can lead to a greater overlap than is the minimum required but is a useful technique to ensure that the overall length of the graft is correct.

It is sometimes the case that the aneurysm extends up to or slightly beyond an arterial bifurcation. In such a case it is possible to place a graft according to the present invention which has a bifurcation at its downstream end, a so-called "trouser graft", wholly within the primary artery. A supplemental graft may then be introduced through each of the subsidiary arteries and overlapped with the respective lumenae of the bifurcated part of the primary graft. In the case of an aneurysm in the aorta, for instance, that extended into each of the iliac arteries the primary graft of the "trouser" type would be placed in the aorta through one of the iliac arteries. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the iliac arteries.

In those cases where one graft according to this invention is to be inserted into the downstream end of another such graft it may be desirable to provide means to stop the "skirt" on the downstream end of the other graft from being distorted by the insertion of the one graft. This may conveniently be done in one or other of two ways. The skirt may be provided with a small number of linear reinforcement wires extending longitudinally of the graft. In this case, the wires are spaced about the circumference of the skirt. Alternatively, the skirt may be provided with at least one resilient annular reinforcement wire. The resilient reinforcement wire will spring into an expanded condition upon being released from the catheter through which it is introduced into the body. This latter arrangement is particularly suitable in the case of "trouser grafts" wherein one leg of the graft will have a skirt which cannot be expanded by a balloon catheter.

BRIEF DESCRIPTION OF DRAWINGS

Hereinafter given by way of example is a preferred embodiment of the present invention described with reference to the accompanying drawings, in which:

FIG. 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by an intraluminal graft according to the present invention;

FIG. 2 is a side elevational view of the intraluminal graft of FIG. 1;

FIG. 3 is a longitudinal sectional view through the intraluminal graft of FIG. 2;

FIG. 4 is a detailed longitudinal sectional view through the intraluminal graft of FIG. 2 as it is being expanded into contact with the aorta of a patient during placement;

FIG. 5 is a detailed longitudinal sectional wire through the intraluminal graft of FIG. 2 after it has been inserted into the aorta of a patient;

FIG. **6** is a detailed elevational view of one end of the intraluminal graft of FIG. **2**; and

FIG. **7** is a detailed perspective view of the one end of the intraluminal graft of FIG. **6** showing how the alternate crests of the end wire of the graft are pushed radially outwardly during insertion of the graft.

BEST MODE OF CARRYING OUT THE INVENTION

The intraluminal graft **10** is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of the aneurysm present in the aorta. As is seen in FIG. **1** the aorta **11** is connected to the left and right femoral arteries **12** and **13**. The aortic aneurysm is located between the renal arteries **14** and **15** and the junctions of the femoral arteries **12** and **13** with the aorta **11**. The graft **10** is, as will be described subsequently in more detail, inserted inside a catheter introduced into one of the femoral arteries **12** or **13** in a leg of the patient. Once the catheter is located appropriately with its proximal end in the aorta **11** the graft **10** is ejected from the catheter and expanded so that each end is in intimate contact around its full periphery with the aorta **11**. The graft **10** then bridges the aneurysm and isolates any thrombosis or gelatinuous material associated with the aneurysm outside the graft **10** to reduce the risk of embolisation.

The intraluminal graft **10** comprises a crimped tube **16** of woven Dacron. The tube is reinforced along its length by a number of separate and spaced apart stainless-steel wires **17** (each of which has a generally closed sinusoidal shape). The wires **17** are preferably as thin as possible and are typically 0.3 to 0.4 mm in diameter. The wires **17** are maleable and may be bent into any desired shape, ie they are not resilient to any substantial extent so that they have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience. The wires **17** are each woven into the fabric of the tube **16** such that alternate crests of each wire **17** are outside the tube **16** with the remainder of that wire **17** inside the tube (except in the case of the endmost wires as will be hereinafter described). The ends of each wire **17** are located outside the tube **16** and are twisted together to form a tail **18**. The tails **18** of alternate wires **17** are bent to extend in opposite longitudinal directions along the outside surface of the tube **16**.

The endmost ones of the wires **17** overhang the respective ends of the tube **17** so that alternate crests of those wires extend longitudinally beyond the end of the tube **16**. The endmost wire **17** preferably has an amplitude of about 6 mm and a wavelength such that between six and eight crests are spaced around the circumference of a 22 mm diameter graft. The next two adjacent wires **18** preferably are spaced as close as possible to the wire **17** and respectively have amplitudes of 4 mm and 5 mm. These wires will typically have the same wavelength initially as the wire **17**. Thereafter throughout the graft **10** the wires **18** are spaced at 15 mm intervals, have an amplitude of 6 mm, and have substantially the same initial wavelength as the wire **17**.

In use the graft **10** is radially compressed about an inflation balloon **19** (see FIG. **4**) and the assembly is inserted into the end of a sheath catheter **21**. The sheath catheter **21** is inserted in a known manner through the femoral artery into the aorta **11** until the proximal end of the catheter **21** is beyond the proximal end of the aneurysm. The balloon **19** and the collapsed graft **10** disposed on it, are held stationary and the catheter withdrawn until the graft **10** is fully exposed and spans the aneurysm. The balloon is then inflated to expand the graft **10**. The diameter of the tube **16** determines

the maximum expansions of the majority of the graft **10** and this diameter has been selected in advance by X-ray examination, or the like, to be substantially equal or only very slightly larger than, the diameter of the undistended aorta **11**. The balloon is, however, able to expand the alternating crests of the end wires **17** so that they are pushed firmly into contact with the wall of the aorta. These radially outwardly displaced crests serve to more effectively restrain the graft **10** against longitudinal movement relative to the aorta.

What is claimed is:

1. A prosthesis comprising:

(i) a bifurcated base structure which defines a common flow lumen and a pair of connector legs which define divergent flow lumens from the common flow lumen; and

(ii) a graft which is adapted to be anchored within one of the flow lumens of said bifurcated base structure to form a continuous extension of that lumen.

2. The prosthesis as defined in claim **1**, wherein said bifurcated base structure is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires.

3. The prosthesis as defined in claim **2**, wherein each of said separate spaced apart wires comprises two opposing ends, said ends being joined together on the outside surface of said bifurcated base structure.

4. The prosthesis as defined in claim **3**, wherein said ends are joined together to form a tail.

5. The prosthesis as defined in claim **2**, wherein at least one of said separate spaced apart wires is interwoven with said bifurcated base structure.

6. The prosthesis as defined in claim **2**, wherein at least one of said separate spaced apart wires is attached to said bifurcated base structure via sutures.

7. The prosthesis as defined in claim **2**, wherein at least one of said separate spaced apart wires is attached to said bifurcated base structure via adhesive.

8. The prosthesis as defined in claim **2**, wherein at least one of the separate spaced apart wires has a different amplitude than a next adjacent wire.

9. The prosthesis as defined in claim **2**, wherein one of the separate spaced apart wires is located at one end of said bifurcated base structure and has alternate crests or apices extending beyond said one end of said bifurcated base structure.

10. A prosthesis comprising:

a first graft comprising a proximal portion, a first distal portion, and a second distal portion;

said proximal portion defining a lumen and adapted to be disposed within a blood vessel in juxtaposition with a bifurcation;

said first distal portion defining a lumen and adapted to allow blood to flow from said proximal portion into a first branched blood vessel;

said second distal portion defining a lumen and adapted to allow blood to flow from said proximal portion into a second branched vessel; and

a second graft defining a lumen and adapted to be intravascularly inserted into a lumen of said first graft to allow blood to flow through the lumen defined by said second graft; and

wherein said first distal portion has a downstream end forming a skirt.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,582,458 B1
DATED : June 24, 2003
INVENTOR(S) : White et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6,
Line 66, insert the following claims:

-- 11. The prosthesis as defined in Claim 1, wherein said graft is circumferentially reinforced at locations along its length by a plurality of separate spaced apart wires.

12. The prosthesis as defined in Claim 11, wherein each of said separate spaced apart wires comprises two opposing ends, said ends being joined together on the outside surface of said graft.

13. The prosthesis as defined in Claim 12, wherein said ends are joined together to form a tail.

14. The prosthesis as defined in Claim 11, wherein at least one of said separate spaced apart wires is interwoven with said graft.

15. The prosthesis as defined in Claim 11, wherein at least one of said separate spaced apart wires is attached to said graft via sutures.

16. The prosthesis as defined in Claim 11, wherein at least one of said separate spaced apart wires is attached to said graft via adhesive.

17. The prosthesis as defined in Claim 11, wherein at least one of said separate spaced apart wires has different amplitude than a next adjacent wire.

18. The prosthesis as defined in Claim 1, wherein material of said bifurcated base structure is crimped along its length.

19. The prosthesis as defined in Claim 1, wherein material of said graft is crimped along its length.

20. The prosthesis as defined in Claim 1, wherein said bifurcated base structure and said graft are formed of a thin biocompatible material.

Signed and Sealed this

Twelfth Day of August, 2003

JAMES E. ROGAN
Director of the United States Patent and Trademark Office